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In re Application of :  
BORODY et al :Decision on Petition  
Serial No.: 10/506,728 :  
Filed : 27 June 2005 :  
Attorney Docket No.:119381-000002/3703US :

This letter is in response to the Petition filed on 25 August 2008 under 37 CFR 1.181 requesting reconsideration of the lack of unity and withdrawal of the restriction made final.

## BACKGROUND

This application was filed as a national stage application under 35 U.S.C. 371. As such, this application is entitled to PCT unity of invention rules.

On 30 November 2007, the examiner required a 10-way lack of unity requirement among the products and processes recited in the original 36 claims. The examiner reasoned that the inventions lacked unity because Kang et al disclosed the special technical feature of a composition comprising a water soluble salt, a water soluble minimally degradable sugar, a water soluble potassium salt and a water soluble magnesium salt.

On 29 May 2008, applicants elected Group I, claims 1-9 and the species of xylose as the minimally degradable sugar with traverse. Applicants also amended claims 1, 3, 4, 12, 13, 35 and 36 and added new claims 37-38.

On 7 July 2008, the examiner considered the traversal. The examiner withdrew the restriction requirement between Group I (product) and Group II (first method of using the first product). The examiner made the restriction requirement FINAL. Claims 12-18 and 34-36 were withdrawn from consideration. Claims 1-7 and 39 were rejected under 35 USC 102(b) as being anticipated by Wolf. Claims 1, 3, 5 and 10-11 were rejected under 35 USC 102(b) as being anticipated by Kawakami. Claims 2, 8-9 and 37-38 were rejected under 35 USC 103(a) as being unpatentable over Kawakami in view of Frauendorfer, further in view of Cockerill.

On 25 August 2008, applicants filed this petition

## **DISCUSSION**

The file history and petition have been considered carefully. The petition requests reconsideration of the lack of unity determination made among Groups I-V.

## **REQUIREMENT FOR UNITY OF INVENTION**

As provided in 37 CFR 1.475(a), an international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an international application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In the lack of unity requirement, the Examiner asserted that the shared technical feature was not a contribution over the prior art in view of Kang et al. This reference was again relied upon in the first Office action on the merits and was the focus of Applicants petition.

This argument is not persuasive in view of the first Office action on the merits, in which the claims have been rejected over prior art as follows:

Claims 1-7 and 39 were rejected under 35 USC 102(b) as being anticipated by Wolf.

Claims 1, 3, 5 and 10-11 were rejected under 35 USC 102(b) as being anticipated by Kawakami. Claims 2, 8-9 and 37-38 were rejected under 35 USC 103(a) as being unpatentable over Kawakami in view of Frauendorfer, further in view of Cockerill.

In view of the outstanding art rejections upon independent claim 1, the technical feature linking Groups I, III, IV and V is not considered to be a contribution over the prior art. For this reason, unity of invention is lacking among Groups I, III, IV and V, a posteriori.

### **When Claims Are Directed to Multiple Processes, Products, and/or Apparatuses:**

Products, processes of manufacture, processes of use, and apparatuses are different categories of invention. When an application includes claims to more than one product, process, or apparatus, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the "main invention" in the claims. In the case of non-compliance with unity of invention and where no additional fees are timely paid, the international search and/or international preliminary examination, as appropriate, will be based on the main invention in the claims. See PCT Article 17(3)(a), 37 CFR 1.475(d), 37 CFR 1.476(c) and 37 CFR 1.488(b)(3).

As provided in 37 CFR 1.475(b), an international application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Groups III, IV and V are directed to methods of treatment for lavage-associated conditions (Group III), acute gastrointestinal infections (Group IV) or constipation (Group V) by administering the composition of claim 1 to a patient in need thereof. Each method requires the technical feature of administered to a particular patient population that is not necessarily co-extensive. For example, it is unlikely that the patient suffering from constipation (Group V) would also be suffering from a gastrointestinal infection (Group IV). As such, unity of invention is lacking a priori among Groups III, IV and V, because each of the methods of Groups III, IV and V require a technical feature not required for the other methods.

The examiner has required restriction between product and process claims. Upon allowance of all claims directed to the elected product invention, applicant may be entitled to rejoinder of process claims. MPEP 821.04 provides concerning rejoinder between product and process inventions.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

## **DECISION**

The petition filed under 37 CFR 1.181 on 27 August 2008 is **DENIED**.

The lack of unity requirement set forth between Group I and Group II was withdrawn by the examiner in the Office action mailed 7 July 2008.

This petition decision maintains the lack of unity requirement set forth between Groups (I and II) and Groups III, IV and V.

Any request for reconsideration should be mailed with two (2) months from the mail date of this decision.

Applicants remain under obligation to respond in a timely manner to the Office action mailed 7 July 2008.

Should all claims to the elected product become in condition for allowance, the examiner will reconsider claims drawn to methods of making or using the allowable product for rejoinder, per MPEP 821.04 and 821.04(b).

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-272-8300.

A handwritten signature in cursive script, reading "George C. Elliott". The signature is written in dark ink and is positioned above the printed name and title.

George Elliott  
Director, Technology Center 1600